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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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| **In re United States Patent Application of:** | | **Docket No.:** | **4354-110** |
| **Applicants:** | **CABANA, Bernard E., et al.** | **Conf. No.:** | **4322** |
| **Application No.:** | **10/668,792** | **Art Unit:** | **1614** |
| **Date Filed:** | **September 23, 2003** | **Examiner:** | **Spivack, Phyllis G.** |
| **Title:** | **RIFALAZIL COMPOSITIONS AND THERAPEUTIC REGIMENS** | **Customer No.:** | **23448** |

**FACSIMILE TRANSMISSION CERTIFICATE**
**ATTN: Examiner Spivack**
**Fax No. (571) 273-8300**

I hereby certify that this document, along with any enclosures identified herein, is being filed in the United States Patent and Trademark Office, via facsimile transmission addressed to Mail Stop Petitions, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, and transmitted on the date specified below, to United States Patent and Trademark Office facsimile transmission number (571)273-8300.

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Number of Pages

Kate Pope

October 21, 2008
Date

**PETITION FOR REVIVAL UNDER 37 CFR 1.137(b); RESPONSE TO OFFICE ACTION AND REQUEST FOR CONTINUED EXAMINATION IN U.S. PATENT APPLICATION NO. 10/668,792**

Attention: Office of Petitions
**Mail Stop Petition**
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

The above-identified application became abandoned for failure to file a reply to an Office

10/22/2008 HMARZI1 00000034 10668792

03 FC:2201 330.00 OP
04 FC:2203 195.00 OP

Office Action. A petition to revive an application abandoned unintentionally under 37 CFR §1.317(b) is enclosed with this response, which responds to the outstanding Final Office Action and requests continuation of the examination for the above-identified application.

Payment of the $810.00 small entity fee for a Petition to Revive specified in 37 CFR § 1.17(m) and the $405.00 small entity fee for a Request for Continued Examination (RCE) specified in 1.17(e) are authorized in the enclosed Credit Card Payment Form PTO-2038.

Please amend the claims of the above-identified patent application as set out in **Section I (Amendments to the Claims)**, beginning on page 3 hereof.

Remarks concerning the amendments to the claims and the substance of the Office Action are set out in **Section II (Remarks)** hereof.

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The PTO did not receive the following listed item(s) Credit Card on Attached Application

**Section I (Amendments to the Claims)**

Please amend claims 2-5 as set out in the following listing of the claims of the application.

1. (Original) A pharmaceutical composition comprising a unit dosage form of rifalazil in an amount between 0.1 and 5 mg.

2. (Currently Amended) ~~The~~ A pharmaceutical composition ~~of claim 1, wherein said~~ comprising a unit dosage ~~comprises~~ form of rifalazil in an amount between 0.1 and 3 mg.

3. (Currently Amended ) ~~The~~ A pharmaceutical composition ~~of claim 1, wherein said~~ comprising a unit dosage ~~comprises~~ form of rifalazil in an amount between 0.1 and 1 mg.

4. (Currently Amended) ~~The~~ A pharmaceutical composition ~~of claim 3, wherein said~~ comprising a unit dosage ~~comprises~~ form of rifalazil in an amount between 0.2 and 0.8 mg.

5. (Currently Amended) The pharmaceutical composition of any of claims 1 through 4 , wherein said unit dosage is a tablet, pill, capsule, or caplet.

6. (Withdrawn) A method of treating a bacterial infection in a patient, said method comprising administering rifalazil to said patient in an amount effective to treat said infection, wherein said rifalazil is formulated in unit dosages comprising between 0.1 and 5 mg of rifalazil.

7. (Withdrawn) The method of claim 6, wherein said infection is selected from the group consisting of a community-acquired pneumonia, upper and lower respiratory tract infection, skin and soft tissue infection, bone and joint infection, hospital-acquired lung infection, acute bacterial otitis media, bacterial pneumonia, complicated infection, noncomplicated infection, pyelonephritis, intra-abdominal infection, deep-seated abcess, bacterial sepsis, central nervous system infection, bacteremia, wound infection, peritonitis, meningitis, infections after burn, urogenital tract infection, gastro-intestinal tract infection, pelvic inflammatory disease, endocarditis, and intravascular infection.

8. (Withdrawn) The method of claim 6, wherein rifalazil is administered for prophylaxis against an infection resulting from a surgical procedure or implantation of a prosthetic device.

9. (Withdrawn) The method of claim 6, wherein said infection is by a Gram positive bacterium.

10. (Withdrawn) The method of claim 9, wherein said bacterium is a Gram positive coccus.

11. (Withdrawn) The method of claim 10, wherein said Gram-positive coccus is drug-resistant.

12. (Withdrawn) The method of claim 11, wherein said infection is by a bacterium selected from the group consisting of S. aureus, S. epidermidis, S. pneumoniae, S. pyogenes, Enterococcus spp., and M. catarrhalis.

13. (Withdrawn) The method of claim 6, wherein said infection is by multidrug resistant bacteria in said patient.

14. (Withdrawn) The method of claim 13, wherein said multi-drug resistant bacteria are penicillin-resistant, methicillin-resistant, quinolone-resistant, macrolide-resistant, or vancomycin-resistant bacteria.

15. (Withdrawn) The method of claim 14, wherein said bacteria are selected from the group consisting of Streptococcus pneumoniae, Staphylococcus aureus, Streptococcus pyogenes, and Enterococcus spp.

16. (Withdrawn) The method of claim 6, wherein said rifalazil is formulated in unit dosages comprising between 0.1 and 3 mg of rifalazil.

17. (Withdrawn) The method of claim 16, wherein said rifalazil is formulated in unit dosages comprising between 0.1 and 2 mg of rifalazil.

18. (Withdrawn) The method of claim 17, wherein said rifalazil is formulated in unit dosages comprising between 0.2 and 0.8 mg of rifalazil.

19. (Withdrawn) The method of claim 6, wherein said rifalazil is formulated as a tablet, pill, capsule, or caplet.

20. (Withdrawn) A method of treating a bacterial infection in a patient, said method comprising administering to said patient between 0.1 and 10 mg of rifalazil over a period of four to fourteen days.

21. (Withdrawn) The method of claim 20, wherein between 0.1 and 5 mg of rifalazil is administered over a period of four to ten days.

22. (Withdrawn) A method of treating a bacterial infection in a patient, said method comprising administering to said patient between 0.1 and 5 mg of rifalazil daily for at least a period of two days.

23. (Withdrawn) The method of claim 22, wherein between 0.1 and 3 mg of rifalazil is administered daily for at least a period of five days.

24. (Withdrawn) The method of claim 23, wherein between 0.1 and 2.6 mg of rifalazil is administered daily for at least a period of ten days.

25. (Withdrawn) The method of claim 24, wherein between 0.1 and 1.6 mg of rifalazil is administered daily for at least a period of thirty days.

26. (Withdrawn) A method of treating a bacterial infection in a patient, said method comprising administering a loading-dose regimen of rifalazil to said patient.

27. (Withdrawn) The method of claim 26, wherein said loading-dose regimen comprises:

a) an initial administration of an average daily dose for 4 to 14 days;

b) following said initial administration, administration of less than half said average daily dose for 4 to 14 days.

28. (Withdrawn) The method of claim 26, wherein said loading-dose regimen comprises an average initial daily dose which is at least 200% of the average daily dose over any of the next